EXPLANATORY MEMORANDUM TO

THE BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2010

2010 No. 745

1. This explanatory memorandum has been prepared by The Health and Safety Executive and is laid before Parliament by Command of Her Majesty.

2. Purpose of the Instrument

2.1 This instrument implements Directive 2009/107/EC by extending the end date of the transitional provisions in the Biocidal Products Regulations 2001 (the BPR), from 14 May 2010 to 14 May 2014. The transitional provisions allow existing biocidal products to remain on the market in Great Britain (subject to existing national legislation) while the active substances contained in them are reviewed at European level for safety and efficacy. Data protection for information submitted on these products and substances is extended by the same period. The instrument also updates certain references in the BPR and adjusts the BPR in the light of operational experience.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Biocidal Products Regulations 2001 (BPR) and the Biocidal Products (Northern Ireland) Regulations 2001 (as amended by the Biocidal Products (Amendment) Regulations 2003; the Biocidal Products (Amendment) Regulations 2005; and the Biocidal Products (Amendment) Regulations 2007) transpose the Biocides Directive.

4.2 There are transitional provisions in the Biocides Directive under which existing products are gradually assimilated into the new regime during a review period. The review was due to be completed by 14 May 2010, but has fallen behind schedule. *Directive 2009/107/EC of the European Parliament and of the Council amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods* (hereinafter referred to as "the amending Directive") puts in place the necessary measures to extend the transitional measures in the Biocides Directive, and the corresponding data protection periods for data submitted for this purpose. The changes being made to domestic legislation will allow existing active substances in the review, and the biocidal products they are used in, to remain on the market in Great Britain (GB) during the extended review period, and will extend the relevant data protection periods. A Transposition Note is attached at Annex A.

4.3 Other changes brought about by this instrument include:

4.3.1 Updating certain references in the Biocidal Products Regulations (BPR) to other legislation where that legislation has changed;

4.3.2 Amending the definition in the BPR of "placing on the market" so that it is consistent with the definition in the Biocides Directive;
4.3.3 Making minor adjustments to two of the timelines for authorisation of products to bring the GB authorisation procedures closer into line with those of the other Member States;
4.3.4 Amending the definition in the BPR of "COPR biocidal product" to ensure that the particular products defined will not be caught by two pieces of legislation once they come to be regulated under the BPR.

5. Territorial Extent and Application

5.1 This instrument applies to Great Britain. Northern Ireland will introduce its own Regulations, which will mirror closely the GB Regulations.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 The Biocides Directive's main objective is the harmonisation of the Member States' legislation and regimes concerning biocidal products. Approximately 800 active substances for use in biocidal products were identified to the European Commission (EC) as being on the market when the Biocides Directive came into force on 14 May 2000. Manufacturers and suppliers of around half of these substances have notified to the EC their intention to support their substances through the review programme. Applications can then be made under the Biocidal Products Regulations (BPR) for authorisations to market biocidal products containing those active substances reviewed and accepted onto Annex I of the Biocides Directive.

7.2 The amendments to the BPR brought about by this instrument will ensure that the existing active substances in the review programme and products containing them can remain on the GB market pending the outcome of the review.

7.3 Public interest is limited largely to the manufacturers and suppliers of active substances and biocidal products already part of the review.

7.4 The legislation is essential to implement the changes to the Biocides Directive brought about by Directive 2009/107/EC. Failure to do so would result in the risk of proceedings in the European Courts and potentially heavy fines for the UK.

- **Consolidation**

7.5 This instrument amends the parent instrument for the fourth time. It was not appropriate to consolidate the legislation on this occasion because of the very tight timescale within which the Directive had to be implemented (it was published in September 2009 and must be implemented by May 2010), and the fact that much of the legislation will be revoked when a European Commission proposal for a directly-acting EC Regulation to replace the Biocides Directive takes effect in 2013.

8. Consultation Outcome

8.1 The consultation ran online for 12 weeks from 1 September 2009 to 23 November 2009. It was widely advertised to those holding HSE approvals for pesticides and everyone registered with HSE to receive information on biocides matters. 106 participants joined in the consultation, 8 participants provided responses to the questionnaire. In almost all cases there was agreement with the proposals, with the exception of one response disagreeing with the proposal for amending the definition of "placing on the market". No reason was given for this disagreement. No other dissenting points were raised.

9. Guidance

9.1 No specific guidance is necessary because the amendments brought about by this instrument make only minor administrative changes to the legislation and do not change the current system or introduce new requirements. Information on the changes will be posted on the HSE website, registered users will be notified via an e-bulletin alert, and the changes will be integrated in the documentation that guides applicants seeking product authorisation.

10. Impact

10.1 An Impact Assessment has not been prepared for this instrument as it has no financial impact on business, charities or voluntary bodies.

10.2 The impact on the public sector is nil.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 None of the provisions of this instrument have any adverse or disproportionate effects on small business, and so no mitigating measures were necessary.

11.3 The small businesses already within the current biocides regime (i.e. all those affected by the amendments) received invitations to participate in the consultation along with the other businesses already within the system.

12. Monitoring and review

12.1 The changes to the transitional end date and corresponding data protection periods will ensure that some 300+ active substances that have yet to be reviewed and the thousands of biocidal products containing them can remain on the market while the review is completed. Without these measures all such substances and products would have to be removed from the market by 14 May 2010.

12.2 The operational changes will ensure that the UK biocides regime is aligned more closely to that of the other Member States, and thus help achieve the aim of the Biocides Directive to harmonise the European biocides regime.

12.3 The outcome will be subject to European review at quarterly meetings of member States' biocides competent Authorities, and will be reported in the 3-yearly

reports to the European Commission as required by Article 24 of the Biocides Directive.

13. Contact

Garry Wiles at the Health and Safety Executive, Tel: 020 7227 3834 or e-mail: garry.wiles@hse.gsi.gov.uk, can answer any queries regarding the instrument.

Annex 1

Transposition Note for DIRECTIVE 2009/107/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods Implemented by the Biocidal Products (Amendment) Regulations 2010		
Article	**Description**	**Transposed by**
1(1)	Amends Article 12 of Directive 98/8/EC dealing with the data protection provisions for information submitted under the Directive for the inclusion of active substances on Annex I of the Directive and for the authorisation or registration of biocidal products containing active substances listed on Annex I. In particular it extends by up to four years the cut-off date for data protection in line with the extended derogations for active substances and biocidal products that are subject to the transitional measures in Article 16 of the Directive. Provision is also made for the further extension of this period by up to two years in line with any decision made under comitology procedures to extend the transitional deadline in Article 16	Regs. 5(c), 6, 7
1(2)	Amends Article 16 of Directive 98/8/EC that provides for a review programme to evaluate all active substances already on the market when the Directive came into force ('existing active substances') to determine whether they satisfy its requirements and can be included on its Annex I, and allows biocidal products already on the market when the Directive came into force to remain on the market under national authorisations provided their active substance(s) have been duly notified to the European Commission as existing active substances. The amendment extends the date the derogation shall cease to apply by four years to 14th May 2014 to allow the review programme to be completed. Provision is also made for the derogation to be further extended if required, by up to two years by comitology decision.	Reg. 5(b) and (c)